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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-------------------------------|---------------|----------------------|---------------------|------------------|
| 10/501,030 | 08/12/2004 | Norbert E. Fusenig | 0471-0286PUS1 | 3120 |
| 2252 | 7590 | 04/01/2008 | | |
| BIRCH STEWART KOLASCH & BIRCH | | | | EXAMINER |
| PO BOX 747 | | | | HENRY, MICHAEL C |
| FALLS CHURCH, VA 22040-0747 | | | ART UNIT | PAPER NUMBER |
| | | | 1623 | |
| | | | | |
| NOTIFICATION DATE | DELIVERY MODE | | | |
| 04/01/2008 | ELECTRONIC | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

| | | | |
|------------------------------|------------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/501,030 | FUSENIG ET AL. | |
| | Examiner MICHAEL C. HENRY | Art Unit 1623 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 26 September 2007.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 18-28 and 30 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 18-28 and 30 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/06/08)
Paper No(s)/Mail Date _____
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) Notice of Informal Patent Application
- 6) Other: _____

DETAILED ACTION

The following office action is a responsive to the Amendment filed, 09/26/07.

The amendment filed 09/26/07 affects the application, 10/501,030 as follows:

1. Claims 11-17 and 29 have been canceled. Upon further consideration it was determined that the indicated allowable subject matter of the prior office mailed 06/26/07 action was not appropriate. Consequently, this allowable subject matter is withdrawn and a new ground(s) of rejection is made herein.
2. The responsive to applicants' amendments and arguments is contained herein below.

Claims 18-28 and 30 are pending in the application

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 18-28 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Willoughby et al. (WO 94/23725) in view of Pressato et al. (WO 97/07833).

In claim 18 applicant claims "A method for the treatment and care of primary and secondary tumors by inhibiting angiogenesis which comprises applying at the tumor site a biomaterial comprised of a benzyl ester of hyaluronic acid wherein said hyaluronic acid is at least 85% benzyl esterified, and wherein said biomaterial inhibits angiogenic processes related to vascularization." Claims 18-28 and 30 are drawn to said method

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wherein said hyaluronic acid is benzyl esterified at specific %, wherein the hyaluronic acid is in association with other natural, synthetic and/or semisynthetic biopolymers, pharmacologically active substance, specific pharmacological active substance, specific forms of the biomaterial and specific form of application to tumor site.

Willoughby et al. disclose the use of hyaluronic acid, including hyaluronic acid esters for the treatment of tumors by inhibiting or regressing angiogenesis (see claims 48-47; see also claims 24-34). Furthermore, Willoughby et al. disclose that their invention provides a process for the inhibition, control and/or regression of angiogenesis, (for example the inhibition of blood vessel growth to a malignant tumour, cutting off blood vessel growth or development, in to a malignant tumour) in a mammal (for example a human), the process comprising the steps of administering an effective dosage amount of a pharmaceutical composition for the inhibition, control and/or regression of angiogenesis to a site on/in the mammal in need of inhibition, control and/or regression (see page 7, lines 6-32; see also page 6, lines 13-21). In addition, Willoughby et al. disclose that

The difference between applicant's claimed method and the method disclosed by Willoughby et al. is that Willoughby et al. do not recite the use of a specific ester (i.e., benzyl ester) of hyaluronic acid but teach that esters of hyaluronic acid can be used.

Pressato et al. disclose a biomaterial comprised of benzyl ester of hyaluronic acid in the form of gels, membranes, woven tissues or meshes and nonwoven tissues that can be used to prevent surgical adhesion (page 5, lines 20-26). This suggests that benzyl ester of hyaluronic acid can be in the form of gels, membranes, woven tissues or meshes

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and nonwoven tissues (of a biomaterial) that can be administered directly to the treated site (page 5, lines 20-26). Furthermore, Pressato et al. disclose that their benzyl ester of hyaluronic acid can be 75-100% esterified (see claim 1). In addition, Pressato et al. disclose that biodegradable and non-biodegradable materials such as polymers in their composition.

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made, in view of Willoughby et al. and Pressato et al., to have used the method of Willoughby et al. to treat tumors by inhibiting angiogenesis with a composition (e.g., a biomaterial) comprising a benzyl ester of hyaluronic acid, since Willoughby et al. suggests that esters of hyaluronic acid can be used by application to the tumor site and Pressato et al. disclose that benzyl ester of hyaluronic acid can be prepared in the form of gels, membranes, woven tissues or meshes and nonwoven tissues (of a biomaterial) that can be administered directly to a treated site.

One having ordinary skill in the art would have been motivated in view of Willoughby et al. and Pressato et al., to have used the method of Willoughby et al. to treat tumors by inhibiting angiogenesis with a composition (e.g., a biomaterial) comprising a benzyl ester of hyaluronic acid, since Willoughby et al. suggests that esters of hyaluronic acid can be used by application to the tumor site and Pressato et al. disclose that benzyl ester of hyaluronic acid can be prepared in the form of gels, membranes, woven tissues or meshes and nonwoven tissues (of a biomaterial) that can be administered directly to a treated site. It should be noted that it is obvious to further include or use pharmaceutically active substance such as antitumor or cancer drugs to treat said tumors.

Response to Arguments

Applicant's arguments with respect to claims 18-28 and 30 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Henry whose telephone number is 571-272-0652. The examiner can normally be reached on 8.30am-5pm; Mon-Fri. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael C. Henry

March 20, 2008.

/Shaojia Anna Jiang, Ph.D./
Supervisory Patent Examiner, Art Unit 1623